

MAY 29 2003

K031011

**SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION**

Valleylab LigaSure™ 5mm Laparoscopic Sealer-Divider

**1. Submitter Information**

Valleylab, Inc.  
5920 Longbow Drive  
Boulder, CO 80301  
Contact: Herbert Vinson  
Telephone: 303-530-6469

Date summary prepared: March 11, 2003

**2. Name of Device**

Trade or Proprietary Name: LigaSure™ 5mm Laparoscopic Sealer-Divider

Common Name: Bipolar Laparoscopic Electrosurgical Instrument

Classification Name:

- Electrosurgical Cutting and Coagulation Device and Accessories, and
- Gynecologic Electrocautery and Accessories

**3. Predicate Devices**

The Valleylab LigaSure™ 5mm Laparoscopic Sealer-Divider is substantially equivalent to the Valleylab LS1000 LigaSure™ LAP Laparoscopic Instrument (K981916), and the Valleylab LS1100 LigaSure ATLAS™ Laparoscopic Sealer-Divider Instrument (K010013). All three of these devices are used in laparoscopic surgery to seal vessels by the application of RF energy to the vessels and tissues interposed between the jaws of the instrument. The LigaSure™ 5mm Laparoscopic Sealer-Divider and the LS1100 LigaSure ATLAS™ Laparoscopic Sealer-Divider Instrument divide tissue using a surgeon-actuated blade.

**4. Device Description**

The LigaSure 5mm Laparoscopic Sealer-Divider is a multi-functional electrosurgical instrument for use with the LigaSure Vessel Sealing Generator (K981916) when performing laparoscopic surgery. The instrument is capable of sealing vessels, dividing vessels and tissue clamped between its jaws, grasping tissue, and blunt dissection. The outer diameter of the instrument shaft is 5mm,

with a working length of 37 cm. Controls are located on the instrument handle. All controls can be operated with either the right or left hand.

The instrument attaches to the generator with a “smart” connector that identifies the instrument type to the LigaSure generator, and a ten (10) foot cable. The instrument is supplied sterile for single-use.

## **5. Intended Use**

The LigaSure™ 5mm Vessel Sealer-Divider is a bipolar electrosurgical instrument intended for use with the LigaSure Generator in general and gynecologic laparoscopic surgical procedures where ligation and division of vessels is desired. The instrument creates a seal by the application of RF electrosurgical energy to vascular structures (vessels) interposed between the jaws of the instrument. A blade within the instrument is actuated to divide tissue.

Indications for use include general laparoscopic surgical procedures including urologic, vascular, thoracic and thoracoscopic, and gynecologic laparoscopic procedures where ligation and division of vessels is performed. These procedures include: laparoscopically assisted vaginal hysterectomy, Nissen fundoplication, colectomy, adhesiolysis, oophorectomy, etc. The LigaSure 5mm Vessel Sealer-Divider has not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures, and should not be used for these procedures.

The LigaSure 5mm Vessel Sealer-Divider can be used on vessels up to and including 7mm diameter, and tissue bundles as large as will fit in the jaws of the instrument.

## **6. Summary of Technological Characteristics**

The LigaSure™ 5mm Laparoscopic Sealer-Divider has the same basic technological characteristics as the predicate devices noted above.

## **7. Performance Data**

Performance testing and pre-clinical studies were performed to ensure that the LigaSure™ 5mm Laparoscopic Sealer-Divider functions as intended, and meets design specifications. Sufficient data were obtained to show that the device is substantially equivalent to the predicate devices, and meets safety and effectiveness criteria.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

**MAY 29 2003**

Mr. Herbert Vinson  
Senior Regulatory Associate  
Valleylab, Inc.  
5920 Longbow Drive  
Boulder, Colorado 80301

Re: K031011

Trade/Device Name: LigaSure™ 5mm Laparoscopic Sealer-Divider  
Regulation Number: 21 CFR 878.4400  
Regulation Name: Electrosurgical cutting and coagulation device and accessories  
Regulatory Class: II  
Product Code: GEI  
Dated: March 11, 2003  
Received: March 31, 2003

Dear Mr. Vinson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

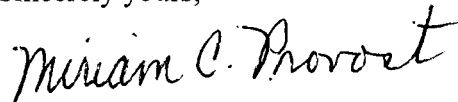
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink that reads "Miriam C. Provost". The signature is written in a cursive style with a large, stylized 'M' and 'P'.

for Celia M. Witten, Ph.D., M.D.  
Director  
Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

510(k) Number (if known): K031011

Device Name: LigaSure™ 5mm Laparoscopic Sealer-Divider

Indications For Use:

The LigaSure™ 5mm Vessel Sealer-Divider is a bipolar electrosurgical instrument intended for use with the LigaSure Generator in general and gynecologic laparoscopic surgical procedures where ligation and division of vessels is desired. The instrument creates a seal by application of RF electrosurgical energy to vascular structures (vessels) interposed between the jaws of the instrument. A blade within the instrument is surgeon-actuated to divide tissue.

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PLEASE DO NOT WRITE BELOW THIS LINE  
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Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)

Division of General, Restorative  
and Neurological Devices

Prescription Use ☒  
(Per 21 CFR 801.109)

510(k) Number K031011

OR

Over-The-Counter Use \_\_\_\_\_

(Optional Format 1-2-96)